REMARKS

Claims 1-12, and 15 -17 are in the application. Claims 1, 2, 8, 9, 11, 12 and 15 have been amended. Claims 16 and 17 have been added. Entry of this amendment into the record is requested.

Claim Objections

Claim 9 is objected to as referring to the specification for the scope of the claimed subject matter. Applicants respectfully traverse this rejection.

As the scope of the Examples in the specification is well defined is not believed that Claim 9 is non enabled nor indefinite.

However, in order to advance prosecution the claim has been amended accordingly.

Support for the examples lies in the working examples and on page 8 therein.

Rejection for Obviousness type Double Patenting

Claims 1 to 12 and 15 are provisionally rejected on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1 to 35 of copending application, USSN 11/576,748.

USSN 11/576,748 is now published as US 2008/0051416. The application claims priority back to 2 US provisional applications filed 4 October 2004 and 22 September 2005 and is therefore considered to be the junior application.

The present application claims priority back to 9 April 2003, and is hence senior to the USSN 11/576,748 application.

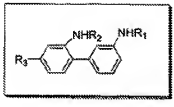
MPEP 804 is quite clear as to the process which should occur herein. In this instance, the earlier-filed application (the instant one) should be permitted to issue as a patent without a terminal disclaimer. The later-filed junior application should be handled accordingly upon examination.

Therefore, in view of these remarks, reconsideration and withdrawal of the rejection to the claims on the grounds of nonstatutory obvious-type double patenting is respectfully requested.

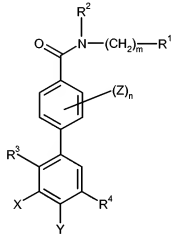
Rejection under 35 USC 103

Claims 1, 4, 5, 7, 8, and 11 are rejected under 35 USC 103 as being unpatentable over Jefferson et al. (WO 02/09648 (hereinafter '648)). Applicants respectfully traverse this rejection.

The Jeffferson et al. '648 application discloses various substituted biaryl/biaryl-heteroaryl compounds for use as antimicrobial agents. The Examiner comments that '648 discloses a particular compound in Table 1, page 20 of the specification. Table 1 is directed to compounds having the following core structure:



In contrast Applicants core structure:



contains the amide on one ring of the biphenyl and the R4 term on the other ring can be -NH-CO-R^7 or -CO-NH-$(CH_2)_p$-R^8. It is only when Applicants amide ring is substituted by Z, and Z is selected from among the many possibilities -$(CH_2)_s$NHCOR^{16}, and specifically R^{16} has to be a C_{1-6}alkyl, which alkyl is optionally substituted by up to two hydroxy groups from among the many possibilities of R16. While Applicants do not agree that one skilled in the art would be motivated to pick and choose amongst the specific variables herein to yield the one compound of the '648 application, Claim 1 has been amended to delete Z as -$(CH_2)_s$NHCOR^{16}. Applicants reserve the right to file divisional or continuation applications on all deleted or cancelled subject matter herein.

Consequently, in view of these amendments the claimed genus herein is not rendered obvious by the teachings or disclosures of the '648 patent application.

Reconsideration and withdrawal of the rejection to the claims under 35 USC §103 is respectfully requested.

Rejection under 35 USC §112, 1st paragraph

Claims 1-12 and 15 are rejected under 35 USC §112, first paragraph as being non-enabling for the term "derivative" (as in pharmaceutically acceptable derivative thereof). Applicants respectfully traverse this rejection.

The Examiner has commented in the Office Action, (6th ¶, page 2) that the specification is enabled for "solvates in the solution phase, salts and prodrugs of hydroxyl, amine or carboxylic acid groups, does not reasonably provide enablement for derivative which are solvates in the isolatable or solid form, other prodrugs, metabolites and residues".

The Examiner comments that there are no examples present within the specification that teach a solid form solvate or hydrate. The term "solvate" is defined as encompassing both solution-phase and isolatable solvates. It is stated by the Examiner that it would "require undue experimentation for one of skill in the art to make the solid and isolatable solvates that are claimed instantly".

Applicants respectfully disagree with the Examiner's conclusions. Simply because they are not stated as being a hydrate does not mean that they are not one. The chemists have not necessarily performed the necessary testing on the compounds to determine such. The primary work of a research and development program such as the one which generated this work is at the bench chemistry level. The medicinal chemists do not "look" for hydrates/solvates unless there is a reason to do so. This activity is a later stage development issue. Using the Examiners reasoning this would imply that each and every one of these compounds, if they formed a solvate would be patentably distinct material because there is no evidence that they exist. It is well within the skilled artisan's ability to determine if a compound is a hydrate. It is not the making of the solvate that the Examiner appears to protest (hence the enablement issue) but that there are no examples demonstrated for a compound of Formula (I). There is no requirement to demonstrate each and every aspect of an invention that a skilled artisan would readily be able to determine.

While it is also believed that the skilled artisan would readily understand that a pharmaceutically acceptable derivative is as defined herein, in particular as a prodrug of hydroxyl, amine or carboxylic acid group, the claims have been amended accordingly to advance prosecution on the merits.

Rejection under 35 USC §112, 1rst paragraph

Claim 12 is rejected under 35 USC §112, 1st paragraph as being enabling for treating inflammation but nonenabling for other conditions mediated by p38 kinase activity or cytokines produced by the activity of p38 kinase. Applicants respectfully traverse this rejection.

The specification provides a lengthy discussion on the role of the p38 kinase and inhibition of the pro-inflammatory cytokines in this pathway. Applicants have previously submitted a number of references which clearly teach the linkage of inhibition of p38 to the treatment of a number of diseases in which this pathway is a factor.

The Examiner presents the Wands factors in the Office Action but disregards the overall fact that no showing of actual treatment of a disease is necessary for a claim related thereto. As the Examiner does note (page 5, 3rd ¶ Office Action), the specification does provide *in vitro* data showing inhibition of the p38 kinase. *In vivo* animal data is not necessary to for establishing the breadth of the claim language.

However, in order to advance prosecution on the merits, Applicants have amended Claim 12 to treatment of inflammation, and will continue prosecution of the deleted or cancelled subject matter in a later filed application.

In view of these remarks and amendments, reconsideration and withdrawal of the rejection to the claims under 35 USC §112, 1rst paragraph is respectfully requested.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case, the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

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